REMARKS

This application has been amended in a manner that is fit to place it in condition for allowance at the time of the next Official Action.

Claims 1-22 are pending in the Official Action. Claims 1-22 have been amended to address the formal matters raised in the outstanding Official Action.

In the outstanding Official Action, claim 17 was objected to for allegedly containing informality. However, applicants amend claim 17 to address the formal matter as suggested by the Examiner. Applicants thank the Examiner for the suggestion as how to overcome the objection.

Claims 3-10 were rejected under 35 USC 112, second paragraph, for allegedly being indefinite. Applicants believe that the present amendment overcomes this rejection.

Claims 3-10 have been amended to provide antecedent basis for the terms objected to by the outstanding Official Action. However, in that the Ginkgo biloba terpenes may be present in either a phospholipid complex or free form (i.e, not in a complex), it is believed that the phrases "free form" and "complex" are definite to one skilled in the art.

Claims 1-14, 17, and 22 were rejected under 35 USC 103(a) as allegedly being unpatentable over CASTELLI, KOCH, and BOMBARDELLI (6,419,950). This rejection is traversed.

CASTELLI relates to dermocosmetic and pharmaceutical compositions which are useful for improving and treating hyperreactive skin conditions. The compositions may contain Ginkgo biloba extracts (col. 4, lines 33-40).

KOCH discloses an extract from parts of Hypericum perforatum L., a method for the preparation thereof, a pharmaceutical preparation and topical medicament containing the extract. The extract may be sued in a gel form to treat skin and mucous membrane irritations and disorders such as acne, atopic dermatitis, neuro-dermatitis, psoriasis, stomatitis, herpes zoster, herpes labialis (lip herpes), warts, varicella (chicken-pox), sores, burns and other disorders that are accompanied by cell proliferation and inflammation (abstract).

BOMBARDELLI (US 6,419,950) discloses the extract of a pericarp of Zanthoxylum bungeanum, prepared by extraction with carbon dioxide in supercritical conditions. The extract allegedly has analgesic activity. The product is prepared by extracting the pericarp of Zanthoxylurn bungeanum into finely ground or transformed into pellets with carbon dioxide under pressure conditions ranging from 150 to 300 bars at temperatures ranging from 35 to 55 C (col. 2, lines 5-55).

However, there is no recognition of a topical composition for the treatment of atopic dermatitis, skin allergic conditions or acne, comprising a combination of Ginkgo biloba

terpenes; floroglucinols, either pure or in mixture thereof, extracted from Humulus lupulus, Hypericum sp and Mirtus sp; and Zanthoxylum bungeanum or Echinacea angustifolia lipophilic extract as recited in claim 1. Indeed, while the publications are directed to skin compositions, there is no recognition that each of the compositions would suitable together.

Furthermore, there is no recognition of a composition with the amounts of components as recited in claim 2. Contrary to the assertions of the Official Action, a particular parameter or variable must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the parameter or variable might be characterized as routine or obvious. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). See also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). As none of the publications recognize the combination and recited amounts, it is believed that one skilled in the art would not consider the combination or amounts as parameters or variables that might be characterized as routine or obvious.

As the Examiner is aware, the Supreme Court recently addressed the issue of obviousness in *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 167 L.Ed.2d 705 (2007). While the *KSR* Court rejected a rigid application of the teaching, suggestion, or motivation ("TSM") test in an obviousness inquiry, the Court acknowledged the importance of identifying "a reason

that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does" in an obviousness determination. *KSR*, 127 S.Ct. at 1731. Thus, as the publications do not provide a reason that would have prompted a person of ordinary skill in the relevant field to combine the publications in a manner so as to obtain the claimed invention, it is believed that the obviousness rejection is improper.

Moreover, the Court indicated that there is "no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis." Id. As long as the test is not applied as a "rigid and mandatory" formula, that test can provide "helpful insight" to an obviousness inquiry. Id.

Indeed, a critical step in analyzing obviousness pursuant to 35 U.S.C. §103(a) is casting the mind back to the time of the invention, to consider the thinking of one of ordinary skill in the art, only guided by the publications and then-accepted wisdom in the field. Adherence to this methodology is important in cases where the invention itself may prompt an Examiner to "fall victim to the insidious effect of a hindsight syndrome, wherein that which only the invention taught is used against its teacher." *In re Kotzab*, 217 F.3d 1365, 1369-70, 55 USPQ 2d 1313, 1362 (Fed. Circ. 2000).

Thus, the fact that the prior art could be so modified would not have made the modification itself obvious unless the

cited publications themselves provide a reason for the modification.

In view of the above, it is believed that CASTELLI, KOCH, and BOMBARDELLI (6,419,950)fail to render obvious the claimed invention.

Claims 1-14 and 17-19 were rejected under 35 USC 103(a) as allegedly being obvious in view of CASTELLI, KOCH, BOMBARDELLI and BOMBARDELLI (US2006/0275246). This rejection is traversed. Applicants submit herewith a verified translation of Italian Application No. MI 2003A 002286, filed on November 24, 2003. In that the filing date of Italian Application No. MI 2003A 002286 is earlier than the publication date and international filing dates of BOMBARDELLI (US2006/0275246), applicants submit that BOMBARDELLI (US2006/0275246) fails to qualify as prior art. Accordingly, applicants request that the rejection be withdrawn.

Claims 20-21 were rejected under 35 USC 103(a) as allegedly being unpatentable over CASTELLI, KOCH, BOMBARDELLI, PARRINELLO and LUPULET. This rejection is traversed.

CASTELLI, KOCH, and BOMBARDELLI fail to render obvious the claimed invention for the reasons noted above. Applicants respectfully submit that PARRINELLO and LUPULET fail to remedy the deficiencies of CASTELLI, KOCH, and BOMBARDELLI for reference purposes.

PARRINELLO was cited for the proposition that extracts of evening primrose and lauric acid may be used in a skin care

system. LUPULET was cited for the proposition that extracts of evening primrose may be utilized in skin cream compositions.

However, neither PARRINELLO nor LUPULET disclose or suggest the particular combination of components or amounts recited in the claimed composition and method.

Thus, it is believed that that the proposed combination of CASTELLI, KOCH, BOMBARDELLI, PARRINELLO and LUPULET fails to render obvious the claimed invention.

In view of the present invention and the foregoing remarks, therefore, applicants believe that the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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Appendix

- Verified translation Italian Application No. MI 2003A 002286, filed on November 24, 2003.